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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/445,193 12/02/99 OHKAWA S 2470US0P **EXAMINER** 023115 HM12/1106 TAKEDA PHARMACEUTICALS AMERICA, INC ROBINSON, B INTELLECTUAL PROPERTY DEPARTMENT ART UNIT PAPER NUMBER 475 HALF DAY ROAD SUITE 500 1625 LINCOLNSHIRE IL 60069 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

11/06/00

1- File Copy



Office Action Summary

Application No.

09/445,193

Ohkawa Et. Al.

Examiner

Binta Robinson

Group Art Unit 1625



Responsive to communication(s) filed on	
☐ This action is FINAL .	
☐ Since this application is in condition for allowance except for formal matters, prosecution a in accordance with the practice under Ex parte Quayle35 C.D. 11; 453 O.G. 213.	s to the merits is closed
A shortened statutory period for response to this action is set to expire3 month(s), or t longer, from the mailing date of this communication. Failure to respond within the period for responsible application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under 37 CFR 1.136(a).	nse will cause the
Disposition of Claim	
X Claim(s) <u>1-24</u>	is/are pending in the applicat
Of the above, claim(s) is/are	withdrawn from consideration
X Claim(s) <u>1-12 and 14-23</u>	
☐ Claim(s)	
☐ Claims are subject to rest	
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.	
☐ The drawing(s) filed on is/are objected to by the Examiner.	
☐ The proposed drawing correction, filed on is ☐ approved ☐disa	pproved.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
🛚 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
X All Some* None of the CERTIFIED copies of the priority documents have been	
🖄 received.	
received in Application No. (Series Code/Serial Number)	
☐ received in this national stage application from the International Bureau (PCT Rule 17	7.2(a)).
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
🗴 Notice of References Cited, PTO-892	
☐ Interview Summary, PTO-413	
□ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	
	,
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

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DETAILED ACTION

- 1. At paper number 7, applicant has made a provisional election to prosecute the compound of Example 4, at page 85 of the specification. The examiner has chosen to broaden the search area and examine the formula in claim 1 where Y is oxygen or sulfur and where R1 and R2 are methyl or ethyl. All subject matter in the claims not drawn to the broadened search area noted above has been withdrawn from consideration.
- 2. Claims 1-12 and 14-23 are Markush claims which are generic to the elected invention.

 The Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.
- 3. Claims 1-12 and 14-23 are rejected on the grounds that the claims are drawn to an improper Markush group. In re Harnish, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural

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similarity in optical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are R, R1, R2, R3, R4, Y and X.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. The term "agent" in lines 1 of claims 19-21 is indefinite because it does not represent a statutory class of invention. The term composition is suggested.
- 5. Claims 15 and 16 are rejected under 37 CFR 1.75 as being a substantial duplicate of each other. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 6. Claims 15 and 17 are rejected under 37 CFR 1.75 as being a substantial duplicate of each other. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one



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claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

- 7. Claims 15 and 18 are rejected under 37 CFR 1.75 as being a substantial duplicate of each other. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

Claims 1, 2, 3, 5, 6, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Takematsu et. al. (Reference A)

Takematsu et. al. teaches the instant compound, Benzofuran, 2, 3-dihydro-2,2-dimethyl-5-(phenylmethoxy)-. At columns 1-156, see the instant compound.

- 9. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstracts, abstract no. 173099g, XP002074285. (Reference U)

 Chemical Abstracts, abstract no. 173099g, XP002074285 teaches the instant compound of formula III, where R2 is NO2. At page 962, see the instant compound.
- 10. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Atsushi et. al. (JP7-247263). (See Reference N)

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Atsushi et. al. teaches the instant endproduct compound at page 507, column 12. At page 507, column 12, see the instant compound.

11. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Baum et. al. (Reference B).

Baum et. al. teaches the instant compounds of examples 100 and 101. At column 7, see examples 100 and 101.

12. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinemann et. al. (Reference O).

Heinemann et. al. teaches the instant compound of example 42. At page 19, Tabelle 1, see example 42.

13. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0165 810 (See Reference P).

EP 0165 810 teaches the instant compound of example 34 A.

14. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cain et. al. (See Reference C).

Cain et. al. teaches the instant compound. At column 15, lines 20-21, see the instant compound.

15. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0733631. (See Reference Q).

EP 0733631 teaches the instant compound in claim 1.

16. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07145147A. (See Reference R).

JP 07145147 A teaches the instant compound as revealed in the abstract.

See the Abstract.

17. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 06312976 A (See Reference S). JP 06312976 A teaches the instant compound as revealed in the abstract. See the abstract.

18. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 03161405A. (See Reference T).

JP 03161405 A teaches the instant compound as revealed in the abstract. See the instant compound in the abstract.

19. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0394043A. (See Reference N1).

EP 0394043 A teaches the instant compound, 67. See claim 1.

20. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0365 925. (See Reference O1).

EP 0365 925 teaches the instant compound as revealed in claim 1. See claim 1.

21. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9105474. (See Reference P1)

WO 9105474 teaches the instant compound as revealed in claim 1. See claim 1.

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22. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 03151311. (See Reference Q1).

JP 03151311 teaches the instant compound as revealed in the abstract. See the Abstract.

23. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 03261778A. (See Reference R1)

JP 03261778A teaches the instant compound as revealed in the abstract. See the Abstract.

24. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04193803

A. (See Reference S1)

JP 04193803 A teaches the instant compound as revealed in the abstract.

25. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0526951

A. (See Reference T1).

EP 0526951 A teaches the instant compound, of example 76.

See claim 1.

26. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 06239853. (See Reference N2)

JP 06239853 teaches the instant compound as revealed in the abstract.

See the abstract.

27. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9509159. (See Reference O2)

WO 9509159 teaches the instant compound as revealed in claim 1. See claim 1.

28. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07179856. (See Reference P2).

JP 07179856 teaches the instant compound as revealed in scheme B. At page 9, see groups CM2, Hal, Ha2, and Hb2.

29. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9734869 A (See Reference Q2).

WO 9734869 A teaches the instant compound as revealed in example 41. See claim 3, example 41.

30. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9529907 A. (See Reference R2)

WO 9529907 A teaches the instant compound as revealed in examples 10-1 and 10-2. See claim 1.

31. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9604251. (See Reference S2).

WO 9604251 teaches the instant compound as revealed in claim 1. See claim 1.

32. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9620925 A. (See Reference T1)

WO 9620925 A teaches the instant compound as revealed in examples 9, 10, 37 and 42. See claim 1.

33. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0778274

A. (See Reference N3)

EP 0778274 A teaches the instant compound, example 120. See claim 1.

34. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 8700840 (See Reference O3)

WO 8700840 teaches the instant compound as revealed in tables, 1, 2, 6, and 7. See claim 1 and tables 1, 2, 6, and 7.

35. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0224816. (See Reference P3)

EP 0224816 teaches the instant compound as revealed in claim 1. See claim 1.

36. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0277842 A. (See Reference Q3).

EP 0277842 teaches the instant compound as revealed in claim 1 and Table 1. See claim 1 and Table 1.

37. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 02233679 A, Abstract. (See Reference R3).

JP 02233679 A, Abstract teaches the instant compound as revealed in the abstract. See the abstract.

38. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9725033 A. (See Reference S3)

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WO 9725033 teaches the instant compound as revealed in claims 1 and 17. See claims 1 and 17.

39. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9610999. (See Reference T3)

WO 9610999 teaches the instant compound as revealed in claims 1. In claim 1, see the instant compound.

40. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9611192 A. (See Reference N4).

WO 9611192 A teaches the instant compound as revealed in claim 1. In claim 1, see the instant compound.

41. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 01199957 A. (See Reference O4).

JP 01199957 A teaches the instant compound as revealed in the abstract. See the abstract.

42. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0445073 A. (See Reference P4).

EP 0445073 A teaches the instant compound as revealed in claims 1 and 4. See claims 1 and 4.

44. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP0686637 (See Reference Q4).

EP0686637 teaches the instant compound as revealed in claims 1, 13, and 16. See claims 1, 13, and 16.

45. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by David et. al. (See Reference V).

David et. al. teaches the instant compound as revealed in scheme 1. See pages 305-309, scheme 1.

46. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Snider et. al. (See Reference W).

Snider et. al. teaches the instant compounds as revealed on page 6597. At page 6597, see the instant compound.

47. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyake et. al. (See Reference X)

Miyake et. al. teaches the instant compound as revealed in scheme I. At page pages 665-674, see the instant compound in scheme I.

48. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsutani et. al. (See Reference U1)

Matsutani et. al. teaches the instant compound as revealed at page 2065. At page 2065, see the instant compound.

49. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by David et. Al. (See Reference V1, Bull. Soc. Chim. Fr.)

David et. al. teaches the instant compound as revealed at Table 1. At pages 527-534, Table I, see the instant compound.

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50. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ponpipom et. al. (See Reference W1).

Ponpipom et. al. teaches the instant compound as revealed in scheme I, charts II and III. At pages 136-142, charts II, III, see the instant compound.

51. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cline et. al. (See Reference X1).

Cline et. al. teaches the instant compound as revealed in Table V.

52. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ratnaker et. al. (See Reference U2).

Ratnaker et. al. teaches the instant compound as revealed in Table 2. At pages 197-200, see Table 1.

53. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et. al. (See Reference V2).

Wang et. al. teaches the instant compound as revealed in figures I and II. At pages 683-686, see figures I and II.

54. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et. al. (See Reference W2).

Clarke et. al. teaches the instant compound as revealed at page 1197. At page 1197, see the instant compound.

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55. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kemp et. al. (See Reference X2).

Kempe et. al. teaches the instant compound as revealed at page 3011. At page 3011, see the instant compound.

56. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwasaki et. al. (See Reference U3).

Iwasaki et. al. teaches the instant compound as revealed in charts I and II at pages 1922-1927. At pages 1922-1927, see the instant compound.

57. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Shipchandler et. al. (See Reference V3).

Shipchandler et. al. teaches the instant compound as revealed in schemes I and II. At pages 67-71, see the instant compound.

58. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Campaigne et. al. (See Reference W3)

Campaigne et. al. teaches the instant compound as revealed at page 298. At page 298, see the instant compound.

59. Claims 1-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaltenbronn et. al. (See Reference X3).

Kaltenbronn et. al. teaches the instant compound as revealed at pages 425-431 in Tables I and II. See the instant compound in Tables I and II.

- 60. The references noted as X references on the International Search Report have been considered. These references have been found to be X references. The Chemical Abstracts no. 225226y reference has been noted as an X reference on the IPER. However, it is not an X reference.
- 61. The IDS filed 3/17/00 has been considered. The references that have been crossed out on the IDS will not be considered until they are supplied to the examiner.
- 62. The elected species in claim 24 appears to be allowable. The first species in lines 4 and 5 of claim 13 also appears to be allowable.
- 63. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta Robinson whose telephone number is (703)306-5437.

The examiner can normally be reached on Monday through Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703)308-0204. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

BMR

SUPERVISORY PATENT EXAMINER

11.11